Preliminary Amendment Serial No.: 08/726,093

Page 4

said separation zone in communication with to said introduction zone and said detection zone.

REMARKS

At the outset, Applicants wish to thank the Examiner for a telephonic interview held on July 14, 1998 with Applicants' representatives Michael H. Brodowski and Isabelle A. S. Blundell. During the interview, Applicants invention as well as the Rose reference was reviewed with regard to claim limitations to denaturing conditions and labeled PNA probes. Amendments to the claims were suggested. References to certain passages of the specification were discussed with respect to the § 112 rejection for the "upstream" limitation. As a result, Applicants submit the aforementioned amendments which reflect the substance of this interview.

Claims 32 to 67 are pending in this application. Claims 32, 45, 46, and 58 are amended herein. Claims 52 and 63 are canceled without prejudice. Accordingly, claims 32-51, 53-62 and 64-67 are presented for examination.

Amendments to Claims

Without acquiescing with the Examiner's bases for rejections of the claims, claims 32, 45, 46, and 58 have been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as their invention. More specifically, claims 32 and 45 now recite that the "at least one single stranded nucleic acid sequence and its complementary strand" are "capable of forming double stranded sections of greater than 50 nucleotide subunits." Support for this amendment can be found in the specification at page 10, lines 7-9.

Claims 46 and 58 now recite the limitation of dependent claims 52 and 63, respectively, i.e., that the PNA probe is "labeled with a detectable moiety." Applicants respectfully submit that no new matter has been added by these amendments.

Rejection of Claims Under 35 USC §§ 102 and 103

Claims 32, 33, 35-37, 39, 40, 42-47, 50-53, 55, and 56 are rejected under 35 USC §102 as being anticipated by Rose ("Rose"). Applicants have amended the independent claims 32 and Preliminary Amendment Serial No.: 08/726,093

Page 5

45 to more particularly point out and distinctly claim the subject matter which Applicants regards as their invention. In particular, these claims now recite that the polynucleotide sample or the single stranded nucleic acid sequence and its complementary strand are capable of forming "double stranded sections of greater than 50 nucleotide subunits." Consequently, Applicants submit that this amendment obviates the rejections based on Rose since Rose only discloses PNA binding with short oligonucleotides of 12 subunits. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 46, 49-51, 54-58, 61, 62, 64, and 67 are rejected under 35 USC §103 as being unpatentable over Wilding et al. in view of Summerton et al. The Examiner pointed out that this rejection had been withdrawn from the claims requiring labeled PNA probe due to persuasive argument of the Applicants. Applicants have amended independent claims 46 and 58 to incorporate the limitation of the dependent claims 52 and 64, respectively, i.e., a labeled PNA probe, and canceled these dependent claims. Applicants submit that this amendment places the above claims in condition for allowance.

Claims 32-37, 39-53, 55 and 56 are rejected under 35 U.S.C § 103(a) as allegedly being unpatentable over Rose taken in view of Chen et al. Applicants respectfully submit that the amendments to the claims obviates this rejection. For the reasons set forth above, Rose does not teach or suggest Applicants invention as is presently claimed. Chen merely teaches analysis procedure for nucleic acids/nucleic acids complexes. Chen does not teach or suggest any PNA/nucleic acid complex formation and analysis. Thus, Chen does not cure the deficiencies of Rose. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Finality of the Office Action

Applicants respectfully request removal of the finality of the Office Action and entry of the above amendments. During the aforementioned interview and prior to the filing of this CPA application, the Examiner informed Applicants that proposed amendments to the claims such as discussed and presented herein may require further searching and thus would not be appropriate for an Amendment After Final. On that basis, Applicants filed a CPA to be afforded the opportunity to amend their application and further prosecute it. However, such opportunity has

Preliminary Amendment Serial No.: 08/726,093

Page 6

been curtailed at great expense to Applicants by the early issuance of this Final Office Action without entry of the discussed amendments.

Thus, Applicants respectfully request that the finality of the outstanding Office Action be removed to permit entry of the above-proposed amendment and consideration of the amended claims.

CONCLUSION

Applicants submit that this Amendment and Reply fully addresses the rejections applied in the Final Office Action mailed on October 1, 1998. Accordingly, Applicants submit that the claim amendments and remarks herein place the claims in condition for allowance and respectfully request early entry of such action.

Respectfully submitted,

Date: December 3, 1998

Reg. No. 43,321

Tel. No.: (617) 248-7634

Fax No.: (617) 248-7100

E-mail: blundell@tht.com

396iasb7783/109.661201

Isabelle A. S. Blundell, Ph.D.

Attorney for Applicant(s)

Testa, Hurwitz, & Thibeault, LLP

High Street Tower

125 High Street

Boston, Massachusetts 02110